K080772

JUN - 3 2008

XI. **510(k) SUMMARY (BoneMedik-DM)**

A. **Submitter:** Tae-Hoon Kim, Manager QM, Meta Biomed Co., Ltd, Cheongwongun Chungbuk, Korea. Tel: 82-43-218-1983.

I. **Classification Name and Number:** Bone Grafting Material 872.3930, LYC

II. **Common/Usual Name:** Dental bone grafting material, bone void fillers

III. **Proprietary Name:** BoneMedik-DM

IV. **Registration No.:** 9681254

V. **Compliance with Performance Standards:** BoneMedik-DM complies with ISO 10993 for biocompatibility, ISO 11137:1995 Sterilization of Health Care Products, requirements for validation and routine control, radiation sterilization; ISO 13779: 2000: ISO 10993: 1997 Biological evaluation of medical devices; ISO 13485 : 2003 Medical Devices, Quality management systems; and ISO 14971 : 2007 Medical Devices - Application of risk management to medical devices. Also, we have followed "Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Dental Bone Grafting Material.

VI. **Description of the Device:** BoneMedik-DM is a coralline hydroxyapatite and a more active tricalcium phosphate bone grafting material for dental and craniofacial usage. It is comprised of 60% silicon substituted hydroxyapatite and 40% β-tricalcium phosphate. The silicon substituted hydroxyl apatite component was cleared for general bone void filling in K070897 by this firm. BoneMedik-DM is an osteoconductive porous implant material which maintains the porous structure of coral and thus is similar in structure to human cancellous bone. The basic material is macroporous and microporous hydroxyapatite and beta tricalcium phosphate, both substances are well known for their bioactivity and ready osseointegration. Both substances are also well known for their excellent bone filler and growth properties. Once implanted, the porous hydroxyapatite and β tricalcium phosphate are resorbed and the reticulated spaces in the implant material are infiltrated with tissue. Bone formation occurs in apposition to the BoneMedik-DM surfaces and within the interstices of the implant skeleton. As the implant resorbs, bone and soft tissue grow into the space previously occupied by the implant. BoneMedik-DM is supplied as granules ranging in size from 0.1 to 2.0 mm. Vials of the powder are available in amounts of 0.25g, 0.5g, 1g, and 2g. The vials are of polyethylene sealed in pouches formed one side of medical grade Tyvek one side polyethylene

VII. **Labels and Labeling:** Draft labels of BoneMedik-DM and instructions for use are provided, together with warnings and contra-indications.

VIII. **Substantial Equivalence:** This device is equivalent to devices manufactured and sold before 1976, having a U. S. classification number 872.3930. Each component is also equivalent to several devices currently on the market that have been cleared by the premarket notification—510(k) process. Some of these are listed below:

1. SynOss Synthetic Bone Graft Material, cleared by Collagen Matrix, Inc., in K072397.
2. OsteoGraf/N-300, cleared by Dentsply, Intl., in K071817,
3. Odoncer, cleared by Teknimed SA in K062102,
4. MBCP Gel, cleared by Biomatlante in K060732,
5. MBCP, cleared by Biomatlante in K051885,
6. OssaPlast Dental, cleared by Ossacur AG in K053374,
7. OsteoGuide Anorganic Bone....cleared by Collagen Matrix in K043034,
8. OsteoGraf/LD-300 Hydroxyapatite, cleared by Ceramed Corp in K960353.

Several of the above cleared bone growth materials are synthetic beta tri-calcium phosphate, like the minor component of BoneMedik-DM. These include Odoncer, cleared by Teknimed SA in K062102;; Ossaplast Dental, cleared by Ossacur AG in 053374; The solid material of MBCP Gel, cleared in K060732 by Biomatlante is 60% hydroxyapatite and 40% beta-tricalcium phosphate, the same ratio as in BoneMedik-DM. The difference from BoneMedik-DM is that MBCP Gel contains this solid material (which was cleared in K051885 by the same company) in an excipient vehicle of hydroxymethylcellulose in an aqueous solution so that it is a gel.

BoneMedik-DM is substantially equivalent to (and nearly identical with) MBCP Gel and MBCP, cleared in 060732 and 051885 by Biomatlante. MBCP (K051885) and the solid material of MBCP Gel (K060732) are 60% hydroxyapatite and 40% β–tri-calcium phosphate. BoneMedik-DM is 60% silicon hydroxyapatite (containing less than 1% silicon) and 40% β–tri-calcium phosphate. The difference is that the silicon hydroxy-apatite portion of BoneMedik-DM is formed by chemical reactions from coral which provides an interconnected porous structure like that of human cancellous bone.
The silicon hydroxyapatite component of BoneMedik-DM is from an animal source (coral with all the organic material removed) substantially equivalent to OsteoGuide Anorganic Bone Mineral Products cleared in K043034 by Collagen Matrix which is from bovine bone with all the organic components removed. This silicon hydroxyapatite component is the same material as that cleared in K070897 by Meta Biomed, Ltd., as BoneMedik-S for general bone void filling. Therefore, both of the components of BoneMedik-DM are substantially equivalent to marketed products and two have substantially equivalents in the same ratio, 60% hydroxyapatite (silicon substituted) and 40% β-tricalcium phosphate of components.

IX. Safety. BoneMedik-DM was evaluated by a number of tests to assess its safety and biocompatibility. It passed all applicable ISO 10993 tests for biological evaluation of medical devices.

X. Effectiveness. Animal testing was conducted to show equivalence of BoneMedik-DM with the most similar, recently 510(k) cleared bone grafting material.

XI. Special Controls Guidance Document. The guidance document, "Guidance for Industry and FDA Staff. Class II Special Controls Guidance Document: Dental Bone Grafting Material," was used to design studies described in this document. These included, among others: (A) Performance Testing, Bench; (B) Animal testing, implantation, (C) Biocompatibility and (D) Sterility.

As discussed above, BoneMedik-DM is substantially equivalent in technical characteristics, intended uses, and safety and effectiveness to the predicate devices cited. The 510(k) "Substantial Equivalence" decision making process (detailed) was followed.

[End of Summary]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2008

Mr. Tae-Hoon Kim
QM Manager
Meta Biomed Company, Limited
414-21 Mo Choong Dong
Chong Ju City
Choong Chong Buk Do
REPUBLIC OF KOREA

Re: K080772
Trade/Device Name: BoneMedik-DM
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: II
Product Codes: LYC, NPM
Dated: February 29, 2008
Received: March 19, 2008

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

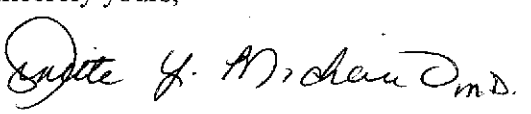
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
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Enclosure

X. Indications for Use: [Separate Page]

510(k) Number: ~~N/A~~ K080772

Device Name: BoneMedik-DM

Indications for use:

BoneMedik-DM is intended for use as a bone grafting material to fill, augment or reconstruct osseous bone defects, in particular in periodontal or oral/maxillofacial application. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. This product may be used in surgical procedures such as:

- Augmentation or reconstructive treatment of the alveolar ridge
- Filling of periodontal defects
- Filling of defects after root resection, apicocectomy and cystectomy
- Elevation of maxillary sinus floor
- Filling of periodontal defects in conjunction with products intended for Guided Tissue regeneration (GTR) and Guided Bone Regeneration (GBR)
- Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration.

Prescription Use__X__ (Per 21 CFR 801 Subpart D) or Over-The-Counter Use_____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K080772